



**Amendments to the Claims:**

This listing of claims will replace all prior versions and listings of claims in the application.

These amendments introduce no new matter and support for the changes is replete throughout the specification and claims as originally filed. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

**Listing of Claims:**

1-6. (Cancelled).

7. (Currently Amended) A pharmaceutical composition for the treatment of diseases in which demyelination of nerve fibers occurs, **the composition** comprising **an amount of nerve growth factor (NGF)[[NGF]]** or **an amount of** an active fragment **thereof of NGF, which fragment is selected from the group consisting of NGF 2.5S, NGF 7S, and an NGF fragment consisting of amino acids 10-25 and 75-88 of NGF linked by a disulfide bridge,** in combination with a pharmaceutical vehicle, auxiliary substance, filler or diluent, **which amount is sufficient to yield a cerebrospinal fluid concentration of from 10 to 300 pg/ml.**

8. (Cancelled).

9. (Currently Amended) The composition according to claim 7, wherein said NGF is human **recombinant** NGF- $\beta$ .

10. (Currently Amended) The composition according to claim 7, further comprising at least one protease inhibitor in an amount sufficient to prevent inactivation of **the NGF or NGF fragment** by proteases.

11. (Original) The composition according to claim 10, wherein said protease inhibitor is aprotinin.

12-15. (Cancelled).

16. (Original) A kit for preventing further demyelination of nerve fibers, comprising NGF and at least one protease inhibitor in separate containers.

### **THE STATUS OF THE CLAIMS**

Claims 7, 9-11 and 16 are pending with entry of this amendment, with claims 1-6, 8 and 12-15 being cancelled herein. Claim 7 is amended herein to more clearly describe the composition claimed. These amendments introduce no new matter and support is replete throughout the specification (e.g., page 3, lines 18-31 and page 2, lines 8-9). The amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Accordingly, entry of the Amendment is respectfully requested.

### **PRIORITY**

The specification is amended herein to more clearly indicate the proper continuity data of the application. As indicated, e.g., on the published PCT application, the current application can also draw priority to USSN 08/833,959, filed April 11, 1997. Thus, the specification is amended herein (i.e., starting at page 1, line 1) to reflect the correct priority. A request for corrected filing receipt is also filed herewith.

### **ELECTION/RESTRICTION**

In order to comply with the Restriction Requirement made final, claims 1-6 and 12-15 (i.e., Group I) are cancelled herein. However, please note that Applicants respectfully reserve the right of subsequent renewal of the claims in their original form. Cancellation of these claims is without prejudice. No intent to abandon any originally claimed subject matter, or intent to acquiesce in any rejection of record should be inferred. Applicants expressly reserve the right to file one or more applications containing the cancelled claims. Elected claims herein, i.e., 7-11 and 16, correspond to Group II.

### **DOUBLE PATENTING**

Claims 7-11 and 16 were provisionally rejected in the Action under 35 U.S.C. §101 for statutory double patenting as claiming the same invention as claims 7-11 and 16 of co-pending application USSN 09/854,142. Applicants respectfully note that claims 7-11 and 16 of USSN 09/854,142 were withdrawn from consideration in that application (i.e., they were

not elected for consideration). Thus, the provisional double patenting rejection of the current claims is moot and Applicants respectfully request that it be withdrawn.

**35 U.S.C. §112, FIRST PARAGRAPH**

Claims 7, 10, and 16 were rejected in the Office Action under 35 U.S.C. §112, first paragraph for allegedly not providing enablement for any “active fragment” or “analogue” of NGF. Applicants first note that only claim 7 recites an “active fragment” or “analogue” of NGF. However, without agreeing to the Office Action’s allegations, Applicants herein amend claim 7 to more clearly define active fragments/analogues of NGF. Support for the changes can be found, e.g., in the specification at page 3, lines 18-31 (i.e., the second full paragraph) as well as in the originally filed claims, e.g., claim 8 (which is cancelled herein due to redundancy with amended claim 7). Applicants believe the amended claims to be enabled by the specification and, thus, request that the rejection be withdrawn.

**35 U.S.C. §112, SECOND PARAGRAPH**

Claims 9-11 were rejected in the current Office Action under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, it was alleged that “recombinant” in claim 9 is vague and indefinite and that claim 10 lacks proper antecedent basis for use of the phrase “further comprising.” Applicants assume that since claim 11 does not recite “recombinant” or “further comprising,” the Office Action should read that claims 9-10 were rejected and proceed accordingly.

Applicants amend claims 9 and 10 herein to remove “recombinant” and “further comprising,” thus, obviating any alleged vagueness or indefiniteness and correcting the lack of antecedent basis. Thus, Applicants respectfully request that the rejection be withdrawn.

**35 U.S.C. §102**

Claims 7-11 and 16 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Althaus (WO 9303140). Applicants amend in part and traverse in part.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. Anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *See* Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983). Applicants respectfully submit that Althaus does not teach every element of the claims as amended. More specifically, Althaus does not teach a composition comprising NGF or an NGF fragment in an amount sufficient to yield a cerebrospinal fluid (CSF) concentration of from about 10 to 300 pg NGF/ml (i.e., as is present in amended claim 7 and its dependents). Additionally, in regard to claim 16 the Office Action has failed to specifically point out where Althaus describes a kit as recited in the current claim.

Claims 7 and 9 were also rejected in the Office Action as being anticipated by Unger et al. (EP 731,108). Applicants submit that Unger also does not teach all of the elements of the currently amended claims (e.g., Unger does not teach a composition comprising NGF or an NGF fragment in an amount sufficient to yield a cerebrospinal fluid (CSF) concentration of from about 10 to 300 pg NGF/ml).

Because of the foregoing arguments and amendments, Applicants believe that neither Althaus nor Unger anticipates the current claims and respectfully request that the rejections be withdrawn.

## **CONCLUSION**

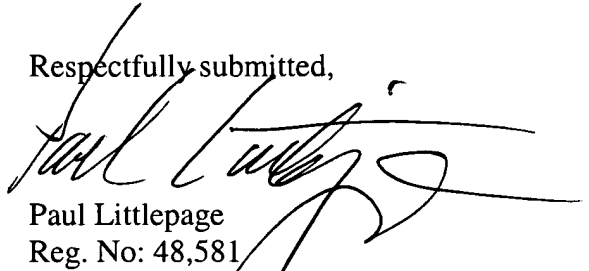
In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3507 to schedule an interview.

Appl. No. 09/529,369  
Amdt. Dated October 14, 2003  
Reply to Office action of **April 14, 2003**.

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Respectfully submitted,



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- 1) A petition to extend the period of response for 3 months (+one copy);
- 2) A transmittal sheet;
- 3) A Request for Corrected Filing Receipt;
- 4) A Marked up copy of the Official Filing Receipt; and,
- 5) A receipt indication postcard.